Application No. 10/796,468
Reply to Office Action from 12/12/2006

REMARKS/DISCUSSION OF ISSUES

Claims 1 - 9 are pending in this application.

Rejections under 35 USC § 103 (a)

Claims 1-9 were rejected under 35 USC 103 (a) as being unpatentable over Wariar et al. (US 7,138,088).

The rejections of the claims are respectfully traversed.

Response to Arguments

To establish a prima facie case of obviousness, three basic criteria must be met. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP 2143).

Before arguing the relevance of prior art, it is worth to reiterate what the present invention claims. The present invention teaches detection of the success of the hypodermic jet injection into a body, through measurement of electric resistance between the body and an injection device, performing this measurement through the jet of liquid itself during the jet injection of a drug or vaccine. Further, the invention teaches that upon penetrating the outermost layer of skin, stratum corneum, having high resistance, the increase of conductivity through the jet of liquid and through the skin is detected and thus the success of the hypodermic jet injection is established. Upon failure of the jet to penetrate the highly resistive stratum corneum, high resistance of this layer of skin results in lower conductivity through the jet and the body and thus failure of the injection process is detected. Thus measurements of the electrical impedance are indicative of the successful penetration of the jet through the skin and into the body upon piercing by the jet of liquid of the

stratum corneum, and said measurements are performed through the jet of liquid during the injection process.

The Wariar et al. reference teaches electric impedance based system for detecting a disconnect or dislodgement of an access device, such as needle, inserted into the patient's body. There is no suggestion or motivation in the reference to measure electric impedance through a jet of fluid, as claimed in the instant invention. Wariar et al. teaches measurements of impedance through a liquid (such as blood) flowing inside the body, inside associated tubes, and inside the access needles. Upon disconnect from the body, the circuit is broken and the disconnect of the needle is detected. Thus Wariar et al. teaches a system which detects disconnect of an access needle from the patient's body by means of monitoring electric impedance. The penetration of the skin to access blood vessels is performed by the said needle, but the penetration of the needle is not being detected by monitoring impedance. The reference fails to teach any jet injection technique, and also fails teach detection of the success of jet injection based on differentiation of conductivity through a jet which has penetrated the skin vs. the jet that has failed to penetrate the skin of the patient, as taught in the instant invention.

The Examiner has suggested that it would have been obvious to one skilled in the art to use a jet injection device to replace the access device or needle as taught in the Wariar reference, or that the jet injection is implicit in, or an obvious variation of, the access device or needle. The Applicants respectfully disagree. Firstly, there is no suggestion or motivation to replace access device during dialysis treatment with a jet injector in the cited art, and the jet of fluid penetrating skin is not implicit in or obvious variation of an access device or needle. Secondly, such arguendo replacement would defeat the intent of the cited art and will render the system taught by Wariar inoperable. Indeed, the dialysis treatment as taught by Wariar involves recirculating the patient's blood using assess devices (needles) through an extracorporeal system (Figs. 1A and 1B) to remove waste, toxins, excess water, etc. from patient's blood. Replacing the needles of the access device with a jet injection device would result in significant amounts of blood spilling on the surface of the patient's skin, and large amounts of blood getting under the skin of the patient but not getting into the correct blood vessels. This will result in the loss of blood, air entrapment, contamination of the patient treatment area with blood droplets, and hazards to the medical personnel working with the patient. Importantly, jet-injected blood will not get into correct recirculation route inside the patient and thus will endanger the patient's life. Moreover, the system taught by Wariar is intended for continuous operation such as dialysis, to timely detect needle

disconnects. Continuously or even intermittently delivering blood into a patient through a transdermal needleless jet injection is hazardous and puts patient's life in immediate danger, as argued above. Further, the Applicants respectfully submit that Wariar et al. reference teaches away from replacing the needle-type access devices with the needleless jet injection. Indeed, the intent of the invention taught by Wariar et al. is to detect blood loss due to dislodgement and to minimize said blood loss by immediate action (e.g. Column 19, 44-59). As argued by the Applicants above, utilizing needle-less injection to inject blood would result in a significant blood loss due to spillage from the jet injection.

Finally, references cited do not teach all of the limitations of the current invention, including measurements of electrical impedance between patient body and jet injector device, closing the electrical circuit through the jet of liquid, and detecting the change in the electrical resistance during the delivery of the drug into the patient's body as a means to monitor the injection success, i.e. penetration of the jet through the stratum corneum, the outer layer of skin.

The Applicants conclude that the reference cited by the Examiner, even with the modification suggested by the Examiner, does not result in the claimed invention. Further, the Applicants respectfully conclude that there is no motivation or suggestion to combine or modify the reference, there is no expectation of success of such modification, and that the reference teaches away from the combination or modification. Thus reconsideration and withdrawal of the rejection of Claims 1 through 9 are respectfully requested.

The Applicant believes that no fees are due in connection with filing of this Office Action reply. The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account 50-3280.

Respectfully submitted:

By:  March 4, 2007

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